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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/756,761
Filing Date: 01/14/2004
Appellant(s): Harbige et al.

FOR APPELLANT
Leonard C.Mitchard
901 North Glebe Road, 11th Floor
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EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/14/2011.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments

The statement of the status of amendments contained in the brief is correct.

(5) Summary of claimed subject matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the issues in the brief is correct.

Grounds of Rejection to be Reviewed on Appeal:

1. The rejection of Claims 1-3, 6-9, 11, 16 under 35 U.S.C. § 103(a) as being unpatentable over Bountra et al. (WO 00/61231, PTO-1449).

2. The rejection of Claims 10, 14-15 under 35 U.S.C. § 103(a) as being unpatentable over Bountra et al. (WO 00/61231, PTO-1449) as applied to claims 1-3, 6-9, 11, 16.

3. The rejection of Claims 1-3, 6-9, 11, and 15 under 35 U.S.C. § 103(a) as being unpatentable over Lunardi et al. (Neurology, volume 48(6), 1997, pages 1714-1717, PTO-892).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied upon

WO 00/61231	Bountra et al.	October 2000
Neurology, volume 48(6), 1997, pages 1714-1717	Lunardi et al.	1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-9, 11, 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bountra et al. (WO 00/61231, PTO-1449).

Bountra et al. discloses a method of treating multiple sclerosis comprising administering sodium channel antagonists such as 3,5-diamino-6-(2,3-dichlorophenyl)-1,2,4-triazine called lamotrigine, 5-amino-6-[2,3,5-trichlorophenyl]-1,2,4-triazine, and compounds of formula (II) with C1-4 alkyl substituents or CF3 groups. See page 7, lines 20-24; page 8, lines 5-10; page 14, claim 7; page 1, lines 15-19; page 3, lines 9-12. Bountra et al. teach that the suitable dose range is for example 0.1 mg/kg to 30 mg/kg bodyweight per day. A dose range of sodium channel antagonist is 200 mg/day to 900 mg/day for an adult human. See page 10, lines 1-8. Bountra et al. also teaches that it may be necessary to make routine variation to the dosage, depending on the age and condition of the patient. See page 10, lines 1-8.

Bountra et al. does not explicitly teach administration of lamotrigine in the method of treating multiple sclerosis i.e does not provide an example.

Bountra et al. does not teach 1, 2, 4-triazine compounds with alkyl substituents such as methyl, ethyl as in claim 16.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer lamotrigine to treat multiple sclerosis because Bountra et al. teach that sodium channel antagonist such as lamotrigine are useful in treating multiple sclerosis. Accordingly, one of ordinary skill in the art would have been motivated to

administer lamotrigine with reasonable expectation of success of treating multiple sclerosis.

Further, regarding the recitations, "wherein the therapy results in reduction of one or more of incidence of relapse, spasticity and fatigue", "wherein the therapy stabilizes the patients Expanded Disability Status Score, thus halting progress of the disease", in claims 8-9, since Bountra et al. render the claimed method of administration of effective amounts of lamotrigine for treating multiple sclerosis obvious, administration of lamotrigine necessarily results in reduction of one or more of incidence of relapse, spasticity and fatigue", halts progress of the disease, as claimed herein.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ triazine compounds containing alkyl substituents in the method of treating multiple sclerosis because Bountra et al. teach structurally similar diazine compounds containing C1-4 alkyl substituents, and trifluoromethyl groups as sodium channel blocker, useful in the methods of treating multiple sclerosis. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to the instant particular triazine compounds containing C1-4 alkyl substituents or trifluoromethyl groups with reasonable expectation of employing them in the method of treating multiple sclerosis.

Claims 10, 14-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bountra et al. (WO 00/61231, PTO-1449) as applied to claims 1-3, 6-9, 11, 16.

Bountra et al. is applied as discussed above.

Bountra et al. discloses a method of treating multiple sclerosis comprising administering sodium channel antagonists such as 3,5-diamino-6-(2,3-dichlorophenyl)-1,2,4-triazine called lamotrigine, 5-amino-6-[2,3,5-trichlorophenyl]-1,2,4-triazine. See page 7, lines 20-24; page 8, lines 5-10. A dose range of 200 mg/day to 900 mg/day for an adult human is disclosed. Bountra et al. also teaches that it may be necessary to make routine variation to the dosage, depending on the age and condition of the patient. See page 10, lines 1-8.

Bountra et al. does not specifically teach the amount of lamotrigine as 600 mg/day as in claim 14, and the dosing regimen as in claim 15.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of lamotrigine to be administered in the method of treating multiple sclerosis.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of lamotrigine employed in the method of treating multiple sclerosis, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of known ingredients in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art at the time of invention would have been motivated to the particular treatment regimen because the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-9, 11, and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lunardi et al. (Neurology, volume 48(6), 1997, pages 1714-1717, PTO-892).

Lunardi et al. discloses administration of lamotrigine to patients suffering from multiple sclerosis in which trigeminal neuralgia was also present. See abstract; page 1715. Lamotrigine was administered at an initial dosage of 25 mg/day, increasing in increments of 25 mg every third day up to a dosage of 400 mg/day. See page 1716, left hand column. Administration of lamotrigine to patients suffering from multiple sclerosis concomitant with trigeminal neuralgia resulted in complete pain relief.

Lunardi et al. does not specifically teach the specific amount of lamotrigine as between 500 mg/day and 700 mg/day.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of lamotrigine to be administered in the method of treating multiple sclerosis.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of lamotrigine employed in the method of treating multiple sclerosis, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of known ingredients in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art at the time of invention would have been motivated to the particular treatment regimen because the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in the art.

Further, regarding the recitations, “wherein the therapy results in reduction of one or more of incidence of relapse, spasticity and fatigue”, “wherein the therapy stabilizes the patients Expanded Disability Status Score, thus halting progress of the disease”, in claims 8-9, since Lunardi et al. render the claimed method of administration of effective amounts of lamotrigine for treating multiple sclerosis obvious, administration of

lamotrigine necessarily results in reduction of one or more of incidence of relapse, spasticity and fatigue", halts progress of the disease, as claimed herein.

(10) Response to Arguments

1. The rejection of Claims 1-3, 6-9, 11, 16 under 35 U.S.C. § 103(a) as being unpatentable over Bountra et al. (WO 00/61231, PTO-1449) should be affirmed.

2. The rejection of Claims 10, 14-15 under 35 U.S.C. § 103(a) as being unpatentable over Bountra et al. (WO 00/61231, PTO-1449) as applied to claims 1-3, 6-9, 11, 16 should be affirmed.

> Appellant argues that "Bountra contains no disclosure or suggestion of the method as claimed. Bountra proposes that sodium channel antagonists may be used to treat multiple sclerosis but by a proposed mechanism of preventing neuronal apoptosis. This is irrelevant to multiple sclerosis (MS), because it is well known in the art that this mechanism is not significant in that disease. Moreover, Bountra contains no disclosure or suggestion of the claimed range of 500mg/day and 700mg/day". See page 9 of the Brief.

In response, it is pointed out that Bountra teaches a method of treating multiple sclerosis comprising administering sodium channel antagonist lamotrigine. See page 7, lines 23-24; page 8, lines 1-5 of Bountra. Bountra also teaches that the sodium channel antagonists can be used at doses appropriate for other conditions for which they are known to be useful. Dosage is varied depending on the age and condition of the patient. Bountra teaches suitable dosage for an adult human is in the range of 200 mg to 900 mg per day.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of lamotrigine to be administered in the method of treating multiple sclerosis.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of lamotrigine employed in the method of treating multiple sclerosis, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of known ingredients in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

One of ordinary skill in the art at the time of invention would have been motivated to the particular treatment regimen because the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in the art.

> Appellant argues that "The Action mailed October 13, 2010 (page 3, lines 3-6) refers to page 10, lines 1-8 of Bountra. However, that passage merely says that, for different sodium channel blockers, the physician should take into account the age and condition of the patient. See page 9 of the Brief.

In response, it is pointed out that Bountra teaches that the sodium channel antagonists can be used at doses appropriate for other conditions for which they are

known to be useful. Dosage is varied depending on the age and condition of the patient. Bountra teaches suitable dosage for an adult human is in the range of 200 mg to 900 mg per day. See page 9, lines 21-25; page 10, lines 1-7. Sodium channel blockers that Bountra is referring to includes lamotrigine. For example Bountra page 9, line 21 refers to EP-0021121-A which contains lamotrigine.

> Appellant argues that "The Action (page 3, line 1) also points to claim 7 of Bountra as a disclosure that sodium channel blockers may be used to treat multiple sclerosis. However, in this regard, attention is again directed to Ramsaransing, et al. (of record) which indicates that carbamazepine, a sodium channel blocker, makes multiple sclerosis worse. For this further reason, one of ordinary skill, as of the filing date of the present case, would not have been motivated to arrive at the presently claimed method based on Bountra." See page 10 of the Brief.

In response, it is pointed out that Lunardi et al. teach that carbamazepine a sodium channel blocker has side effects. Lunardi further teaches that the sodium channel blocker lamotrigine has a better side effect profile. Lunardi teaches that administration of lamotrigine to patients suffering from multiple sclerosis concomitant with trigeminal neuralgia resulted in complete pain relief. See Lunardi et al. Neurology, volume 48(6), 1997, pages 1714-1717, which is employed in the second 103(a) rejection. It is pointed out again as discussed above that Bountra teaches a method of treating multiple sclerosis comprising administering sodium channel antagonist lamotrigine. See page 7, lines 23-24; page 8, lines 1-5 of Bountra. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to employ sodium channel blocker lamotrigine in treating multiple sclerosis.

3. The rejection of Claims 1-3, 6-9, 11, and 15 under 35 U.S.C. § 103(a) as being unpatentable over Lunardi et al. (Neurology, volume 48(6), 1997, pages 1714-1717, PTO-892) should be affirmed.

> Appellant argues that "Referring to the obviousness rejection of claims 1-3, 6-9, 11 and 15 over Lunardi, that reference states that all of the patients had been on carbamazepine at 200 to 1500 mg/day prior to lamotrigine treatment, but that this treatment had been stopped due to serious side effects. In contrast, Appellants have discovered, surprisingly, that the dosage may be increased to avoid adverse effects (specification, paragraph [0023])." See page 10 of the Brief.

In response, it is pointed that Lunardi et al. discloses administration of lamotrigine to patients suffering from multiple sclerosis in which trigeminal neuralgia was also present. See abstract; page 1715. Lunardi et al. teach that carbamazepine a sodium channel blocker has side effects. Lunardi further teaches that the sodium channel blocker lamotrigine has a better side effect profile. Lamotrigine was administered at an initial dosage of 25 mg/day, increasing in increments of 25 mg every third day up to a dosage of 400 mg/day. Lunardi et al. also teach that optimal dosage needs to be determined. See page 1716, right hand column. Accordingly, one having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of lamotrigine employed in the method of treating multiple sclerosis, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of known ingredients in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Appellant's arguments, and the Declaration of Dr. Jacqueline Palace filed on 04/19/2010 have been considered, but not found persuasive.

The Declaration of Jacqueline Palace states that "As a physician having extensive knowledge and experience of MS, I do not agree that patients should be prescribed lamotrigine at doses as high as 900 mg. I base this statement on my review of the doses tolerated in Dr Kapoor's recent lamotrigine trial in secondary progressive MS, where the highest tolerated dose was 300 mg (average only 78 mg) in this population. Indeed, the protocol stated a maximum dose of 400 mg, and I note that this was the maximum dose in the Lunardi study". These remarks have been considered, but not found persuasive. The declaration under 37 CFR 1.132 has been fully considered but is ineffective to overcome the 103(a) rejection herein as to nonobviousness over the prior art, since the declaration merely presents statements, conclusion or speculations or opinions regarding the claimed invention, i.e., the doses tolerated in Dr Kapoor's recent lamotrigine trial in secondary progressive MS, where the highest tolerated dose was 300 mg lysergol, but fails to set forth any factual evidences. Therefore, the declaration is insufficient to rebut the prima facie case herein. It is pointed out that applicant did not provide the cited Dr. Kapoor's reference. Further, it is

pointed out that Lunardi et al. also teach that optimal dosage needs to be determined. See page 1716, right hand column.

Appellant's arguments with respect to side effects have been considered. It pointed out that Guberman et al. teaches that the prescription of lamotrigine, as with all other drugs should be undertaken with appropriate consideration of the potential risks to the patient in relation to potential benefits i.e one needs to exercise caution in using lamotrigine as with any other drug. See page 989 of Guberman et al.

Appellant's remarks regarding papers such as Leandri et al., Solaro et al., Silver et al., Titlie et al. etc., it is pointed out that the papers cited do not state that the maximum dose one can employ in the treatment of multiple sclerosis is 400 mg/day of lamotrigine. For example, it is pointed out that Solaro et al. reference (Neurol Sci 2005), provides data for administration of lamotrigine at 150 mg/day, and 170 mg/day only. From, the data provided by Solaro one cannot conclude that the maximum tolerated dosage is 400 mg/day, since nowhere does Solaro et al. teach that. The same is true for the papers such as Leandri et al., Silver et al., Titlie et al. etc.

Bountra et al. clearly discloses that sodium channel antagonists which includes lamotrigine are used for treating multiple sclerosis. Bountra broadly teaches a dose range of sodium channel antagonists therein which include lamotrigine as 200 mg/day to 900 mg/day for an adult human. It would have been obvious to a person of ordinary skill in the art at the time the invention to determine the effective amounts of lamotrigine employed in the method of treating multiple sclerosis, since the optimization of effective amounts of known agents to be administered, is considered well in the competence

level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art, and further Bountra teaches that it may necessary to make routine variations to the dosage. One of ordinary skill in the art at the time of invention would have been motivated to the particular treatment regimen because the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in the art.

Appellant's arguments, and the Declaration of Professor Giovannoni filed on 05/25/2010 have been considered, but not found persuasive as discussed below.

Applicant's remarks that "Professor Giovannoni declares that in his opinion, at the time of the present invention, an experienced neurologist in this art such as himself would not have contemplated administering LTG to a patient suffering from MS in dosage levels higher than the recommended maximum of 400mg daily. Professor Giovannoni's reasoning (paragraph 8) is that LTG is neuroprotective in animal models of global and focal ischaemia *in vivo* at doses of 20mg/kg and above, i.e., greater than 4X the anticonvulsant dose in rats (although the ED50 is 2mg/kg, the rat anticonvulsant ED95 is approximately 5mg/kg." These remarks have been considered. First, it is pointed out that the cited references do not teach that one should not use LTG at a dosage higher than 400 mg/day in treating multiple sclerosis. Second, Professor Giovannoni teaches "LTG is neuroprotective in animal models of global and focal ischaemia *in vivo* at doses of 20mg/kg and above" i.e for a 60 kg human it is 1200 mg. Thus, one can employ greater than 400 mg/day of LTG.

Appellant argues that "In paragraph 12, the Giovannoni declaration states that doses of LTG lower than 400mg per day have been used to treat central pain in patients with MS, and that in the paper by Leandri and colleagues (Lamotrigine in trigeminal neuralgia secondary to multiple sclerosis, Leandri et al., 2000. iNeurol. 247:556-558), doses of 25mg daily to a maximum of 400mg daily were used." These arguments have been considered, but not found persuasive because Leandri et al., does not teach that one should not use LTG at a dosage higher than 400 mg/day for the treatment of multiple sclerosis. Leandri teaches that complete pain relief resulted at doses between 75 and 400 mg/day, and thus suggests that a maximum dosage of 400 mg/day is sufficient for the treatment therein which is trigeminal neuralgia pain.

Appellant argues that "In paragraph 16, Professor Giovannoni concludes that, in light of the published facts prior to the present invention and the subsequent US patent filing in 2004, it would not have been obvious to him or any other neurologist with skill in the art of administering LTG that doses higher than the recommended maximum of 400mg daily could be effective to modify the course of the progressive pathology of MS to the extent exhibited in the patent application." These arguments have been considered, but not found persuasive because the published facts cited by applicant do not teach that one should not use LTG at a dosage higher than 400 mg/day in treating multiple sclerosis. Bountra et al. clearly discloses that sodium channel antagonists which includes lamotrigine are used for treating multiple sclerosis. Bountra broadly teaches a dose range of sodium channel antagonists therein which include lamotrigine as 200 mg/day to 900 mg/day for an adult human. Bountra also teaches that the sodium

channel antagonists can be used at doses appropriate for other conditions for which they are known to be useful. Dosage is varied depending on the age and condition of the patient. It would have been obvious to a person of ordinary skill in the art at the time the invention to determine the effective amounts of lamotrigine employed in the method of treating multiple sclerosis, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art, and further Bountra teaches that it may be necessary to make routine variations to the dosage. One of ordinary skill in the art at the time of invention would have been motivated to the particular treatment regimen because the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of known ingredients in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Further, Appellant's declarations under 37 CFR 1.132, are insufficient to overcome the rejection under 35 U.S.C. 103(a) for the following reasons. It has been held that any unexpected/surprising results submitted to rebut the prima facie case, the scope of the showing must be commensurate with the scope of the claims. *In re Coleman*, 205 USPQ 1172; *In re Greenfield*, 197 USPQ 227; *In re Lindener*, 173 USPQ 356; *In re Payne*, 203 USPQ 245. Note that the claims include several compounds of formula I, and not just lamotrigine.

Appellant argues that "Lunardi likewise does not suggest treatment of multiple sclerosis using the claimed dosage level. Thus, taking Bountra alone, or in combination with Lunardi, the physician would not have been motivated to arrive at the presently claimed dosage of between 500mg/day and 700mg/day and, in fact, would have acted to reduce the dosage in the case of multiple sclerosis patients based on the state of the art."

These arguments have been considered, but not found persuasive as discussed above. One of ordinary skill in the art at the time of invention would have been motivated to the particular treatment regimen because the optimization of result effect parameters e.g., dosage range, dosing regimens, dosing duration is obvious as being within the skill of the artisan, involving merely routine skill in the art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, it is believed that the rejections should be sustained.

(11) Related Proceedings Appendix
None

Respectfully submitted,

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Conferees

/Shobha Kantamneni/

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